LWQIC Meeting Minutes
Monday, March 20, 2006 **10 – 11 am** **Room 123**

Attendees: Dina Caloggero, Steve Ridley, Glen Krumholz, Dr. Han, Kathy Nawn, Tanya Rivera, Nancy Tisei, Paul Elvin, Julie Nassif, Scott Hennigan, Sandy Smole, Dr. George, John Fontana, Peggy DiNatale

Minutes prepared by: Peggy DiNatale, 4/18/06

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1. **Corrective action review**:
   Paul Elvin : TB-05-001
   The laboratory participated in a nucleic acid amplification proficiency survey from CAP. This survey contains only educational challenge specimens. The result submitted by the Mycobacteriology Lab for one of the specimens did not agree with the intended response. A review of the documentation associated with the test run demonstrates that all procedures were followed, the controls were acceptable and the test interpretation was correct. The lab has been experiencing problems with the Genprobe MTD assay. All of the problems are documented in the problem log and the lab continues to document it's ongoing communications with the company.
   Past studies have demonstrated good correlation between results obtained using the Genrpobe MTD assay and culture techniques. The MTD assay is a screening tool and is not the sole basis for patient diagnosis. For these reasons, no procedural changes will be implemented at this time.

2. **CLIA personnel categories for each Laboratory**
   a. **Revised Personnel CLIA form**
      The CLIA personnel form was revised and the current version is now on the F common drive in the Quality Assurance folder, under the Personnel folder (F: common/Quality Assurance/Personnel). This revised form was distributed at the meeting. In the Personnel folder, the document title is: Lab Personnel Qual Appraisal Form.
      Revisions to the form include:
      1. Maiden name removed from the form
      2. The CLIA titles were updated to reflect current CLIA titles
      3. Functional Title section was renamed SLI Functional Title and the titles reflect current SLI titles
      4. The Clinical Laboratory Experience section was revised to reflect the subspecialties at SLI and the work experience section requests that work experience be listed beginning with the most recent work experience.

   b. **We need to revise the Staff Lists for each laboratory for 2006**. We will discuss the CLIA regulations for the various Laboratory Specialties and their respective Subspecialties, relative to Technical Supervisor and Technical Consultant titles.

3. **Centralizing the Safety and QA SOPs and how to incorporate these into the Annual SOP Index for each laboratory.**

The Safety SOPs are on the F common drive in the Safety folder. The QA SOPs are on the F common drive in the Quality Assurance folder. The SOP Index form will be reformatted to accommodate SOP titles that contain greater than 35 characters. This form will eventually be on the F common drive in the Quality Assurance folder and in the SOP folder.

Annually the labs must submit a list of lab specific SOPs and Safety and QA SOPs that are relevant for their specific lab. QA will place a central SOP inventory list on the F common drive for the Safety SOPs and the QA SOPs. These inventory lists will contain a column that labs will check off for relevant SOPs. QA will notify Lab Supervisors when these lists are available for use.

4. **Requesting Changes to Test Reports**

When the laboratory wishes to make changes to the test reports, LIS and QA need to coordinate to ensure that the changed reports continue to meet the CLIA reporting regulations. QA has developed a form that will be completed by the Laboratory Director or Supervisor to initiate the review process. A copy of the form was distributed at the meeting. QA will write an SOP that will outline how requests for changing test reports will be processed. This form has been used by a couple of labs and revisions have been suggested.